

## Message Text

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ORIGIN EA-12

INFO OCT-01 ISO-00 COME-00 EB-08 TRSE-00 CIAE-00  
INR-10 NSAE-00 STR-07 HEW-06 L-03 OES-09 CTME-00  
/056 R

DRAFTED BY EA/EP:JSHINN:SRP  
APPROVED BY EA/EP:RWARNE  
EA/J:HCOCHRAN  
COMMERCE:DBUSSINGER  
-----094107 120238Z /14  
R 111848Z JUL 78  
FM SECSTATE WASHDC  
TO AMEMBASSY TOKYO

UNCLAS STATE 174450

E.O. 11652: N/A

TAGS: BEXP, ECEM, ETRD, JA

SUBJECT: US PHARMACEUTICAL FIRMS IN JAPAN

REF: TOKYO 11033

1. ON JULY 6 STATE AND COMMERCE REPRESENTATIVES LED BY  
DAS HEGINBOTHAM MADE TWO HOUR PRESENTATION AND DISCUSSION  
WITH INTERNATIONAL ADVISORY COMMITTEE (IAC) OF  
PHARMACEUTICAL MANUFACTURERS ASSOCIATION (PMA) TO EXPLAIN  
FINDINGS OF INVESTIGATION OF NTBS FACED BY US  
PHARMACEUTICAL FIRMS IN JAPAN. IAC IS COMPOSED OF SENIOR  
EXECUTIVES WITH FAR EAST MARKET RESPONSIBILITY OF MAJOR  
US PHARMACEUTICAL FIRMS.

2. USG PRESENTATION WAS BASED ON CONTENTS OF REFTEL.  
MANY IAC MEMBERS DID NOT AGREE WITH CONCLUSION PARA. 3-A  
OF REFTEL THAT LITTLE DISCRIMINATION EXISTS IN MHW  
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APPROVAL PROCESS. SEVERAL MEMBERS WERE VEHEMENT IN  
ASSERTIONS THAT EXTENSIVE DISCRIMINATORY BUREAUCRATIC  
DELAYS ARE CONSISTENTLY ENCOUNTERED BY US FIRMS IN NEW  
DRUG APPROVAL (NDA) PROCESS, AND SEVERAL SPECIFIC  
INSTANCES WERE CITED. THERE WERE TWO DISSENTS FROM THIS  
VIEW.

3. FOLLOWING AN EXPLANATION OF TFC AND TSG MECHANISMS BY USG REPS, IAC MEMBERS DEBATED BEST METHOD OF SEEKING REDRESS. ONE VIEW WAS THAT A COOPERATIVE NON-ADVERSARY METHOD OF DISCUSSION WITH MHW IS MOST DESIRABLE, AND THAT MEMBERSHIP IN JAPAN PMA COULD BE A SIGNIFICANT STEP IN THIS APPROACH. ANOTHER VIEW WAS THAT GENERIC TFC CASES COULD BE PRESENTED BUT THAT INSUFFICIENT MATERIAL NOW EXISTS TO PROCEED WITH SUCH A PROGRAM. IAC CHAIRMAN CONCLUDED DISCUSSION BY SUGGESTING FURTHER DISCUSSION WITHIN IAC AND PMA TO CONCLUDE IF SUFFICIENT MATERIAL COULD INDEED BE GATHERED AND TO CONSIDER POSSIBLE PROGRAMS TO DO SO. IAC PROMISED TO CONTACT USG REPS IN NEAR FUTURE WITH RESULTS OF THIS DISCUSSION AND THANKED USG REPS FOR POSITIVE APPROACH AND INFORMATION.

4. EMBASSY IS REQUESTED TO AIRMAIL COPIES OF EMBOFF MEMCONS WITH PHARMACEUTICAL FIRM EXECUTIVES IN JAPAN AND TO MAINTAIN PERIODIC CONTACT WITH THEM PENDING FURTHER RESPONSE FROM PMA.

CHRISTOPHER

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NNN

## Message Attributes

**Automatic Decaptioning:** X  
**Capture Date:** 01 jan 1994  
**Channel Indicators:** n/a  
**Current Classification:** UNCLASSIFIED  
**Concepts:** DRUGS, BUSINESS FIRMS, FOREIGN INVESTMENTS  
**Control Number:** n/a  
**Copy:** SINGLE  
**Draft Date:** 11 jul 1978  
**Decaption Date:** 01 jan 1960  
**Decaption Note:**  
**Disposition Action:** n/a  
**Disposition Approved on Date:**  
**Disposition Case Number:** n/a  
**Disposition Comment:**  
**Disposition Date:** 01 jan 1960  
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**Disposition History:** n/a  
**Disposition Reason:**  
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**Document Number:** 1978STATE174450  
**Document Source:** CORE  
**Document Unique ID:** 00  
**Drafter:** JSHINN:SRP  
**Enclosure:** n/a  
**Executive Order:** N/A  
**Errors:** N/A  
**Expiration:**  
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**Original Handling Restrictions:** n/a  
**Original Previous Classification:** n/a  
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**Reference:** 78 TOKYO 11033  
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**Review Release Event:** n/a  
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**Status:** NATIVE  
**Subject:** US PHARMACEUTICAL FIRMS IN JAPAN  
**TAGS:** BEXP, ECEM, ETRD, JA, US  
**To:** TOKYO  
**Type:** TE  
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**Review Markings:**  
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